K100994

ATTACHMENT 4

510(K) SUMMARY

Submitter's Name, Address and Date of Submission

APR 30 2010

Tina M. Wittchow
Vice President, Professional & Technical Services
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110

Phone: 651-653-8512
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Submitted: April 8, 2010

Device Name

Trade Name:	[Trade Name] Preloaded Tissue Marker Device
Classification Name:	Implantable Clip, 21 CFR 878.4300
Common/Usual Name:	Tissue Marker

Predicate Device

BiomarC Preloaded Tissue Marker Device (K042296)
BiomarC Tissue Marker (K063193)

Indication for Use

[Trade Name] Preloaded Tissue Marker is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Device Description

[Trade Name] Preloaded Tissue Marker Device is a sterile, nonpyrogenic, single use tissue marker consisting of pyrolytic carbon coated zirconium oxide discrete marker that is visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound and Magnetic Resonance Imaging (MRI) incorporated into lyophilized BiomarC Delivery Gel. The [Trade Name] Preloaded Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

Technological Characteristics and Performance

The technological characteristics are equivalent to the predicate devices. A Failure Modes and Effects Analysis (FMEA) was performed in order to assess the risks associated with the modifications introduced. Biocompatibility testing, sterility validation, distribution simulation and shelf life testing results confirmed that the modified device, [Trade Name] Preloaded Tissue Marker Device, was substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Carbon Medical Technologies, Inc.
% Ms. Tina M. Wittchow
VP, Professional & Technical Services
1290 Hammond Road
St. Paul, Minnesota 55110

APR 30 2010

Re: K100994
Trade/Device Name: Preloaded Tissue Marker Device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: April 8, 2010
Received: April 9, 2010

Dear Ms. Wittchow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100994

Device Name: [Trade Name] Preloaded Tissue Marker Device.

Indications for Use:

[Trade Name] Preloaded Tissue Marker is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100994